



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,818	08/22/2001	Jean-Michel Bernardon	016800-451	7237

7590

02/12/2002

Norman H. Stepno, Esquire
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,818

Applicant(s)

BERNARDON ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of PCT/FR00/03646 which claims priority to FR 99/16270.

Election/Restrictions

Applicant's election with traverse of the invention of the species of the active compound in claim 14 (compound 3 at page 4 in the specification) in Paper No. 6 submitted January 25, 2002 is acknowledged.

The traversal is on the ground(s) that no undue burden is placed upon the Office to search and examine all other species represented by the structural formula (I) herein. This is not found persuasive. As discussed in the Restriction Requirement mailed December 28, 2001, claims 1-21 read on the employment of various compounds of with great diversity of chemical structure classified across class 514, the search for all of which presents an undue burden on the Office. It is noted that a reference to one individual agent would not be a reference to another individual agent under 35 U.S.C.103.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on the elected specie.

Claim Objection

Claims 7-8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s)

Art Unit: 1617

in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that recitation of an inherent property of a composition or method will not further limit claims drawn to a composition or method. In the instant case, for example, "PPAR receptor activator" in claims 7-8 is an inherent property of the composition herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for those particular compounds disclosed in the specification (see, e.g., page 9 of the specification herein) in methods herein, does not reasonably provide enablement for the employment any "chiral analogs" and "derivatives".

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,

- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

In the instant case, the expressions "chiral analog" in claims 1-2 and 18-19, "derivative", in claims 17 and 20-21 may encompass any "chiral analogs" and "derivatives", "agents for combating free radicals", and "ion channel blockers". However, Applicant's specification provides the experimental results showing that only five particular Compounds 1-5, are tested for transactivation of receptors of PPAR type (see page 9 of the specification). Thus, these examples fail to provide sufficient working examples to support the broad use of any any "chiral analogs" and "derivatives" in the claimed pharmaceutical compositions. Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, the instant claims read on the employment any "chiral analogs", "derivatives", "agents for combating free radicals", and "ion channel blockers" in pharmaceutical compositions, necessitating one of skill to perform an exhaustive search for the embodiments of any "chiral analogs" and "derivatives" suitable to practice the claimed invention. Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working

examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention absent undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "regime or regimen" in claims 1-17 renders claims 1-17 indefinite. The expression "regime or regimen" is not defined in the specification. Therefore, the claims is unclear as to whether a "regime or regimen" may be considered as a composition or a method of treating.

In order to expedite prosecution, claims 1-17 will be examined as a composition as has apparently been intended (see page 5-6 in the specification herein).

The expression "such period of time...the desired response" in claims 1-2 renders claims 1-17 indefinite. The expression "such period of time...the desired response" is not defined in the specification and claim. The scope of the claims is indefinite as to what may be considered as the "desired response" and how long of "such period of time" is.

Claims 7-8 contains the trademark/trade name "PPAR". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material

Art Unit: 1617

or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular receptor activator herein and, accordingly, the identification/description is indefinite.

The expressions in claims 9-12, for example, "compound (I) comprising at least one linear or branch alkyl radical..." in claim 9, renders claim 9-12 indefinite since it is unclear which substituent in the structural formula herein, i.e., R₁, R₂...or R₈ have this linear or branch alkyl radical in claim 9 or other groups in 10-12.

The expressions "chiral analog" in claims 1-2 and 18-19, "derivative", "agent for combating free radicals", and "ion channel blocker" in claims 17 and 20-21 render claims 1-21 indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1617

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernardon (5,763,487, PTO-1449 submitted August 22, 2001).

Bernardon discloses that the active instant compounds including the particular elected compound (see col.3 lines 50-53) are useful in pharmaceutical compositions and tablets, suspension, ointment, cream, and lotion for a wide variety of diseases in humans or veterinaries such as dermatological, cardiovascular, and skin and hair conditions/disorders. See abstract, col.1-2, col.3 lines 50-53, Example 20 at col.16 and claims 12-25. Bernardon also discloses the employment of retinoids, particular vitamin D compounds, corticosteroid, particular α -hydroxy or α -keto acids, and ion channel blockers in the combination with the instant compounds in the pharmaceutical compositions therein (see col.6 lines 67). Bernardon further discloses that the administered route is enteral, parental, topical, and ocular (see col.7-8). Thus, Bernardon anticipates the claimed invention.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

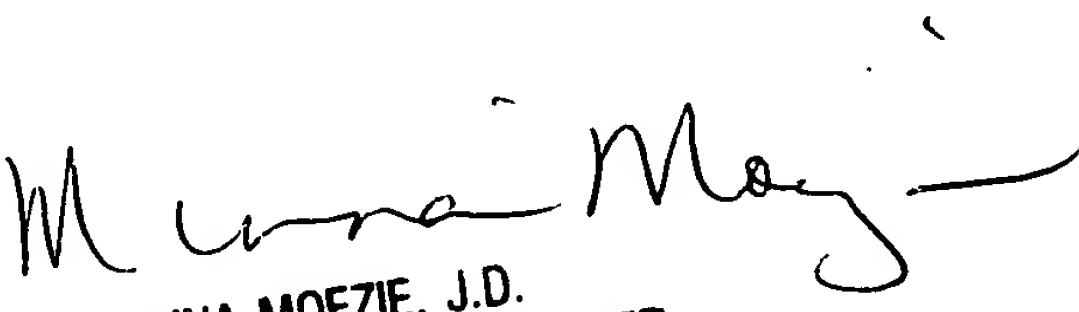
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone

Art Unit: 1617

number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
February 7, 2002


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600